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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,119

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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,119	Applicant(s) JANSSENS ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 19-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 19-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-7 and 19-35 are currently pending and are the subject of this Office Action.

Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, and constitute the complete set presently being applied to the instant application. Applicants' remarks filed Mar. 3, 2009 are acknowledged. Applicants' arguments are moot in light of the new grounds of rejection applied herein.

Claims 19-25 are currently indicated as withdrawn. In light of the withdrawal of the restriction requirement in the Office Action dated Nov. 3, 2008, these claims are included in the set under examination. A new claim set should be submitted in response to this Office Action clearly setting forth the proper status of all claims per C.F.R. 1.121(c).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 5, 19, 20, 22, 23, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over BALOG (Balog, J. M. (2003). *Avian and Poultry Biology Reviews*, 14(3); pp. 99-126; 1st NPL Ref. on IDS dated Jan. 19, 2007) in view of Emmessar Biotech & Nutrition Ltd. Webpage (hereinafter EMESSAR; available Dec. 4, 2000).

1. Balog teaches that ascites syndrome, first noticed in poultry raised at high altitude, has become a significant problem for poultry producers everywhere, and is now prevalent everywhere that broilers are raised (title; abstract; p. 100, 1st col., lines 28-29

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p. 102, 2nd col., section 3.1; p. 115, right col., lines 7-8). Balog teaches that a number of factors including, *inter alia*, altitude, oxygen pulmonary hypertension, contribute to ascites, but that all of these factors cause ascites by inducing hypoxia in the bird (abstract; Fig. 1). In fact, Balog teaches that the primary stimulus of ascites is believed to be hypoxia (p. 100, 1st col., lines 13-15). Balog emphasizes that the high growth rate in modern broiler chickens results in a high demand for oxygen (abstract; p. 100, 1st col., 2nd paragraph; p. 102, last paragraph; p. 106, lines 13-14; p. 107, section 4.3.2). Balog states that the initial event in the development of ascites can come in many forms, but the ultimate factor is an inadequate oxygen supply (p. 102, 1st col., 1st sentence of last paragraph) and that oxygen requirement is the most critical trigger of ascites in broilers (p. 109 1st col., 1st sentence of last paragraph).

2. Emmessar teaches that dimethylglycine (DMG) is a modified amino acid that is found in any living body. Emmessar teaches that in its primary action, DMG helps in absorption, transport, and delivery of oxygen to the cells of the body and that DMG is an enhanced provider of vital oxygen to the individual cells of the body (p. 3 under item 2, entitled How does DMG work?). Emmessar teaches that DMG is used to help transport oxygen to mitochondria. Emmessar further teaches that DMG functions to increase work output, as an anti-stress nutrient, and immune response potentiator, and as an antioxidant. Emmessar teaches that one use of DMG is as a nutritional feed supplement for humans and animals and states that by virtue of its property of being an oxygen provider to the cells of the body it has the following applications as a nutritional supplement: as a feed supplement for, *inter alia*, poultry for the purpose of

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enhancement of athletic performance, disease free growth through higher immunity, high meat quality, imparting resistance to various diseases in, *inter alia*, poultry farms, etc. (p. 4 under item I, entitled End use as a nutritional feed supplement for humans and animals). Furthermore, Emmessar teaches that DMG can help prevent cancer and other diseases by supplying sufficient oxygen to body cells.

3. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to add DMG to poultry feed, to provide a treatment for ascites in broiler chickens. One would have been motivated to do so because Balog teaches that inadequate oxygen (i.e. hypoxia) is the primary cause of ascites and since Emmessar teaches that DMG is useful as a poultry feed supplement to enhance oxygen absorption and delivery. Further, one would have a high expectation of success since Emmessar also teaches that DMG can increase resistance to various diseases. The combination of Balog and Emmessar renders claims 1, 2, 4, 5, 19, 20, 22, 23, 33, and 34 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention

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as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balog and Emmessar as applied to claims 1, 2, 4, 5, 19, 20, 22, 23, 33, and 34 above, and further in view of COOK (U.S. 6,852,333; Issued Feb. 8, 2005).

4. The teachings of Balog and Emmessar are presented *supra*. Balog teaches that, in an attempt to curb ascites syndrome, a large effort has been put forth in determining dietary manipulations that will decrease ascites incidence (p. 107, section 4.3.5). Emmessar teaches that DMG is useful as a feed supplement for, *inter alia*, poultry (p. 3). While neither reference explicitly teaches incorporation of DMG into drinking water, such would readily have been envisioned by the skilled artisan.

5. For example, Cook discloses compositions and methods for enhancing production gains in broiler chickens by employing anti-stress agents that may be supplied in animal foodstuffs or water (col. 6, lines 49-50). Moreover, Cook teaches that typical feed conversion (FCRs) for broiler chickens are less than 2.5, even under stress conditions (Fig. 8). Moreover, Cook presents data that suggest broiler chickens under stress that have been treated with an anti-stress composition approach and even surpass the efficiency of feed conversion to weight gain observed in unstressed control birds.

6. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to add DMG to poultry feed or water, to provide a treatment for ascites in broiler chickens. One would have been motivated

to do so because Cook establishes that addition of agents to the drinking water of livestock is an acceptable means for administering treatment compounds. Furthermore, DMG is a known anti-stress agent as taught by Emmessar. Thus, one would have been motivated to use it under conditions of low FCR and high growth rate (which Cook establishes are typical) to ease the stress on the animals as taught by Cook. The combination of Balog, Emmessar, and Cook renders claims 21 and 25 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balog, Emmessar, and Cook as applied to claims 1, 2, 4, 5, 19, 20, 22, 23, 33, and 34 above, and further in view of MOLLY (WO 03/043440; Published May 30, 2003).

1. The teachings of Balog, Emmessar, and Cook are presented *supra*. Cook teaches that anti-stress agents can be administered in a broad effective range and that appropriate dosages can be selected by the skilled reader according to known protocols

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(col. 8, lines 54-57). However, Cook explicitly teaches dosages in terms of g/kg and does not explicitly teach the amounts in % wt of the feed. It would be routine for the skilled artisan to determine the optimal amount of DMG to add to animal feed compositions, particularly given the disclosure of Cook.

2. The MPEP states that, "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2144.05.

3. Moreover, inclusion of feed additives in the instantly claimed ranges was conventional at the time of the invention. For instance, Molly discloses compositions and methods for improvement of growth, reducing feed conversion, and/or for improving health of animals comprising including various additives in animal feeds (abstract). The compositions can be used as feeds for poultry (p. 10, lines 12-16). When used in animal feeds, the compositions of the invention are used in a range of 0.01-20% by weight of the feed, and in a range of 0.1-5% in one embodiment (p. 9, last paragraph to p. 10, line 10).

4. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use DMG as a supplement for poultry feed as taught by Cook, in the instantly claimed wt. % ranges, which are taught

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in the art as conventional. The combination of Balog, Emmessar, Cook, and Molly renders claim 24 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 1-6, 26-31, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over COOK (U.S. 6,852,333; Issued Feb. 8, 2005) in view of ZHANG (U.S. 6,875,890; Filed Jun. 29, 2004).

5. Cook discloses compositions and methods for enhancing production gains in animals by employing anti-stress agents (abstract). Cook teaches that various infections and diseases are a major concern for agricultural livestock production as these conditions contribute to stress and subsequent weight loss in the animals (col. 1, lines 14-60). Cook teaches that many of the disadvantages associated with these issues can be addressed by reducing animal stress levels (col. 1, lines 61-63; col. 2, lines 30-33 and 58-60; col. 3, lines 6-13). The animals treatable with anti-stress agents

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include chickens (col. 5, lines 31-40; Experiment 7), and the oral administration may be achieved by supplying the agent in animal foodstuffs or water (col. 6, lines 49-50). Specifically, Cook states that anti-stress treatment of broiler chickens increases growth rate by reducing the stress response and increasing the efficiency by which feed was converted into body weight (col. 17, lines 5-24). Cook teaches that typical feed conversion (FCRs) for broiler chickens are less than 2.5, even under stress conditions (Fig. 8). Moreover, Cook presents data that suggest broiler chickens under stress that have been treated with an anti-stress composition approach and even surpass the efficiency of feed conversion to weight gain observed in unstressed control birds (FCRs of less than 2.5) (col. 17, lines 19-24). Cook teaches that preferred classes of anti-stress agents include amino acids (col. 8, lines 8-12). Cook does not teach the instantly recited glycine compounds as anti-stress agents.

6. However, Cook teaches that any appropriate anti-stress compounds known in the art may be employed in the invention (col. 7, lines 65-67). Zhang discloses a process for preparing DMG, and teaches that DMG is known as a nutritional supplement that helps the body adapt to various forms of stress (abstract; col. 1, lines 44-46). Zhang explicitly teaches that DMG is an anti-stress nutrient: "The nutritional and physiological properties of DMG come from it being an Ergogenic (tending to increase work output) substance, an anti-stress nutrient, a cell antioxidant, and an immune response potentiator."

7. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use DMG as a supplement for

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poultry feed as taught by Cook, to provide a suitable anti-stress feed additive for broiler chickens. In doing so, one would be merely substituting equivalents known for the same purpose (i.e. anti-stress compounds). Such substitution of active agents is clearly within the skill of the ordinary artisan. Furthermore, the MPEP states that "An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)." See MPEP § 2144.06(II). The combination of Cook and Zhang renders claims 1-6, 26-31, 33, and 35 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 7 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook in view of Zhang as applied to claims 1-6, 26-31, 33, and 35 above, and further in view of MOLLY (WO 03/043440; Published May 30, 2003).

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8. The teachings of Cook and Zhang are presented *supra*. Cook teaches that anti-stress agents can be administered in a broad effective range and that appropriate dosages can be selected by the skilled reader according to known protocols (col. 8, lines 54-57). However, Cook explicitly teaches dosages in terms of g/kg and does not explicitly teach the amounts in % wt of the feed. It would be routine for the skilled artisan to determine the optimal amount of DMG to add to animal feed compositions, particularly given the disclosure of Cook.

9. The MPEP states that, Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2144.05.

10. Moreover, inclusion of feed additives in the instantly claimed ranges was conventional at the time of the invention. For instance, Molly discloses compositions and methods for improvement of growth, reducing feed conversion, and/or for improving health of animals comprising including various additives in animal feeds (abstract). The compositions can be used as feeds for poultry (p. 10, lines 12-16). When used in animal feeds, the compositions of the invention are used in a range of 0.01-20% by weight of the feed, and in a range of 0.1-5% in one embodiment (p. 9, last paragraph to p. 10, line 10).

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11. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use DMG as a supplement for poultry feed as taught by Cook, in the instantly claimed wt. % ranges, which are taught in the art as conventional. The combination of Cook, Zhang, and Molly renders claims 7 and 32 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

Claims 1-7 and 19-35 are rejected. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643